UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

PENN Orthopaedic Institute

Department of Orthopaedic Surgery

Gerald R. Williams, M.D.
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Reconstructive Surgery of
the Shoulder and Elbow

December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NO. 97N-484S

To Whom It May Concern:

It has recently come to my attention via an allograft procurement company that the above-mentioned docket could result in allograft material being regulated as a medical device. I do not know what the intention of this proposal is; however, it has wide reaching ramifications, some of which I think would be disastrous to patients in the United States. We use allograft bone on numerous occasions to help us replace bone in patients who are missing it. Situations in which this may be used include revision joint replacements, post-traumatic fracture work, spinal fusions and fusions involving other joints. My understanding is that the FDA already regulates the safety of these tissues. I can't think of why the FDA would want to regulate their use as a medical device and require such things as sponsoring clinical trials. The added expense of this, I am certain, would impede companies and bone banks from providing an adequate supply of this material. The FDA should look long and hard at this proposal and assess all of its ramifications.

Sincerely,

Gerald R. Williams, Jr., M.D.
Associate Professor of Orthopaedic Surgery

97N-4845 C83

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